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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/829,511	04/22/2004	Rangarajan Sundar	P1070 US	7340

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MEDTRONIC VASCULAR, INC
3576 UNOCAL PLACE
SANTA, ROSA, CA 95403

EXAMINER	
DOWE, KATHERINE MARIE	
ART UNIT	PAPER NUMBER
3734	

MAIL DATE	DELIVERY MODE
02/24/2010	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/829,511	SUNDAR, RANGARAJAN	
	Examiner	Art Unit	
	KATHERINE M. DOWE	3734	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE *3* MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 November 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1,2,4-7 and 9-35* is/are pending in the application.

4a) Of the above claim(s) *11-32* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1,2,4-7,9,10 and 33-35* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

1. The following is a complete response to the amendment filed November 17, 2009.

2. Claims 1, 2, 4-7, and 9-35 are currently pending, with claims 11-32 withdrawn from consideration.

Double Patenting

3. Claims 1, 2, 4-7, 9, 10, and 33-35 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claim 3 of copending Application No. 10/827,817. In the copending application, claim 3 is dependent on claim 1. For double patenting to exist as between the rejected claims and copending application claim 3, it must be determined that the rejected claims are not patentably distinct from claim 3. In order to make this determination, it first must be determined whether there are any differences between the rejected claims and claim 3 and, if so, whether those differences render the claims patentably distinct.

Claims 1, 2, 4-7, 9, 10, and 33-35 recite a “catheter” (see line 2 of claim 1 of the copending application as amended July 20, 2009), a balloon operably attached to the catheter” (see line 3 of claim 1 of the copending application), “a stent disposed on the balloon” (see line 4 of claim 1 of the patent), “a silane layer” (see lines 8-9 of claim 1 of the copending application), and “a coating disposed on the silane layer” (see lines 6-7 of claim 1 of the copending application) including “a therapeutic agent” (see lines 1-2 of claim 3 of the copending application) and a “polymer” (see line 10 of claim 1 of the copending application)

It is clear that all the elements of claims 1, 2, 4-7, 9, 10, and 33-35 are to be found in claim 3 (as it encompasses claim 1). The difference between claims 1, 2, 4-7, 9, 10, and 33-35 of the application and claim 3 of the copending application lies in the fact that the copending

application claim includes many more elements and is thus much more specific. Thus the invention of claim 3 is in effect a "species" of the "generic" invention of claims . It has been held that the generic invention is "anticipated" by the "species". See *In re Goodman*, 29 USPQ2d 2010 (Fed. Cir. 1993). Since claims 1, 2, 4-7, 9, 10, and 33-35 are anticipated by claim 3 of the copending application, it is not patentably distinct from claim 3.

4. This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Claim Rejections - 35 USC § 102

5. The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.

6. Claims 1, 2, 4-7, 9, 10 and 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Rowland et al. (US 5,356,433, hereinafter "Rowland"). Rowland discloses a stent disposed on a balloon catheter (col 2, ll 64-68). The stent comprises a stainless steel frame (col 4, ll 35-39), an amino silane layer (col 4, ll 40-62) disposed on the stent, and a polymer coating layer including a therapeutic agent disposed on the silane layer (col 5, ll 22-64). The polymer coating may comprise heparin (col 5, ln 48-49).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

8. The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

9. Claims 34 and 35 are rejected under 35 U.S.C. 103(a) as being unpatentable over Rowland (US 5,356,433), as applied to claims 1 and 6 above, further in view of Sagiv (US 4,539,061). Rowland discloses the invention substantially as claimed as shown above. However, Rowland does not disclose the thickness of the silane layer. Sagiv discloses a similar system comprising a substrate layer (col 3, ll 26-33; analogous to the stent of Rowland), an intermediate silane layer (col 4, ll 13-15), and biologically active compound coupled to the surface of the intermediate layer (col 6, ll 45-47). The intermediate layer is formed as a monolayer with individual monolayers formed on top of one another on the surface of the substrate (col 2, ll 43-57; col 8, ll 7-9; col 11, ll 30-62). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the device of Rowland such that the silane layer comprised multiple monolayers as taught by Sagiv to ensure the entire stent, or substrate, comprised the polymer coating which is applied over the silane layer. Furthermore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the combination of Rowland and Sagiv such that the silane layer comprised 8 to 10 monolayers, since it has been held that where the general conditions of a claim are disclosed in the prior art, discovering the optimum or workable ranges involves only routine skill in the art. In re Aller, 105 USPQ 233. Alternatively, it would have been prima facie obvious to try modifying the silane layer of Rowland such that the thickness of the silane layer

was 8-10 monolayers in an attempt to provide an improved coated stent as a person with ordinary skill has good reason to pursue the known options within his or her technical grasp and since it is obvious to choose from a finite number of identified, predictable solutions with a reasonable expectation of success.

Response to Arguments

10. Applicant's arguments filed November 17, 2009 have been fully considered but they are not persuasive.

11. Applicant argues Rowland does not disclose a polymer coating disposed on the silane layer. The Examiner respectfully disagrees. Rowland clearly teaches a biologically active layer covalently linked to the silane layer disposed on the stent (col 5, ll 22-64). Specifically, the biologically active layer may comprise heparin, which is a polymer.

12. Regarding claims 4 and 9, Applicant argues Rowland does not disclose the silane layer is selected from the group consisting of a monolayer, a multilayer, and a bulk phase layer. The Examiner respectfully disagrees. Rowland clearly discloses applying a silane layer to the stent surface, and thus inherently the silane layer must be at least a monolayer or multilayer.

Conclusion

13. Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after

the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

14. Any inquiry concerning this communication or earlier communications from the examiner should be directed to KATHERINE M. DOWE whose telephone number is (571)272-3201. The examiner can normally be reached on M-F 8:30am - 5pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Todd Manahan can be reached on (571) 272-4713. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Katherine Dowe
February 17, 2010

/K. M. D./
Examiner, Art Unit 3734

/Todd E Manahan/

Supervisory Patent Examiner, Art Unit 3734